Pharma&Biotech

Lonza

Lonza Clinical Technologies

Your Trusted Partner in Regenerative Medicine

Cell and Gene Therapies,
Clinical iPSCs and Derived Cell Types,
Therapeutic Media, Testing Solutions

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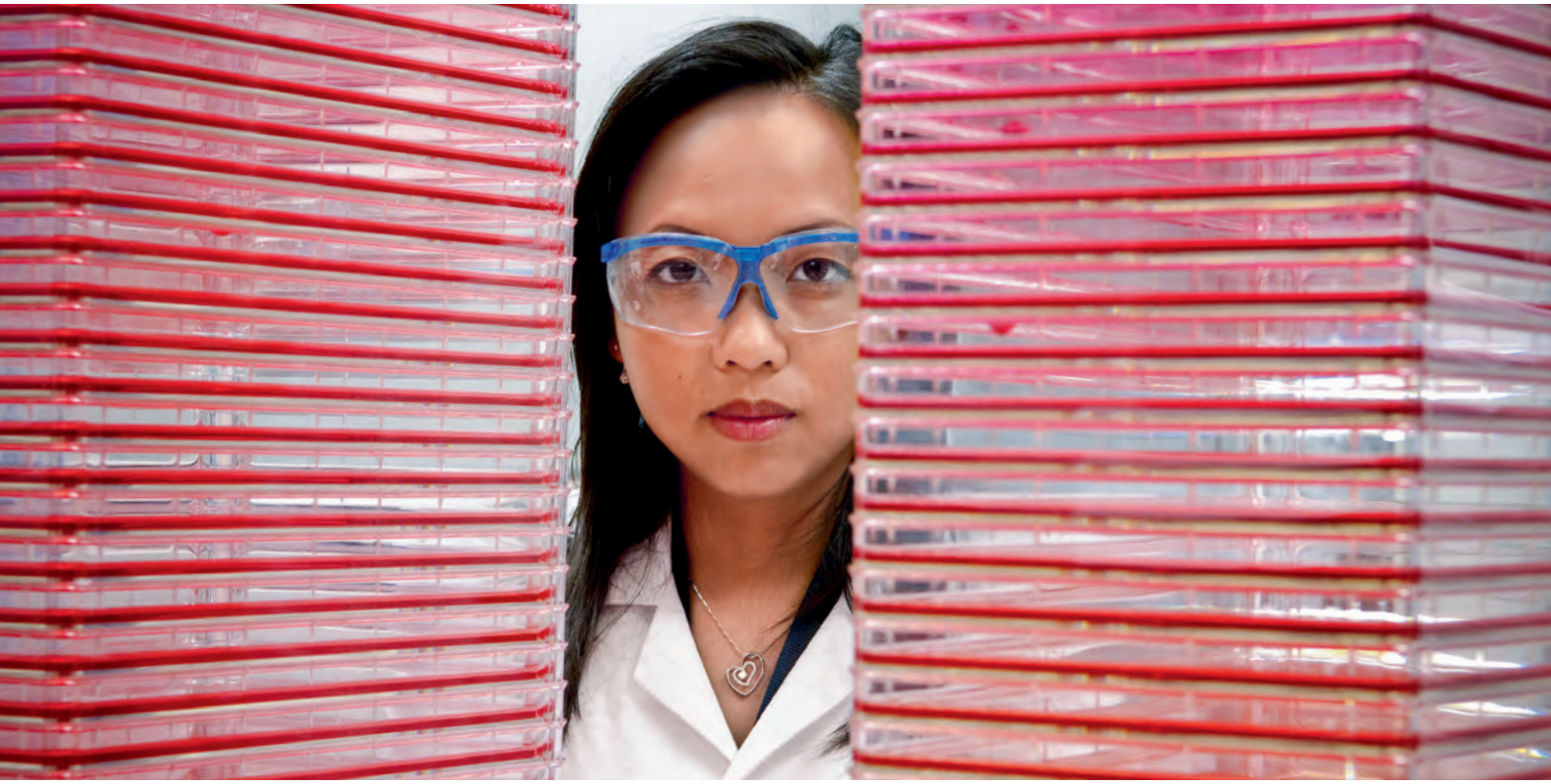

Cell Therapy

Lonza's commitment is to provide high quality personalized service to support the rapid clinical development and commercial manufacturing of cellular therapeutics. Our global leadership in custom manufacturing for the pharmaceutical industry offers world-class current Good Manufacturing Practices (cGMP) with scalable capacity, flexible scheduling and personalized service. A team of technical professionals will work diligently to help you source tissues, improve processes, and implement cost-effective manufacturing technologies for autologous and allogeneic therapies.

www.lonza.com/celltherapy

Tissue Acquisition

Let Lonza's expert team help you navigate the complexities of tissue sourcing logistics and regulatory hurdles. As an AATB accredited, FDA registered and state licensed tissue bank, we provide the support you need. Our team of experienced tissue banking professionals builds specific donor, tissue and cell programs to accommodate each client's unique plans. To assist clients in complying with current donor eligibility requirements, the tissue acquisition team develops programs in accordance with 21 CFR Part 1271 (HCT/P) while helping to ensure the ethical sourcing of human tissue. Our clients may reference Lonza's Human Tissue and Cells Donor Programs Type V DMF in their regulatory submissions to the US FDA.

« Your Product. Our Passion. »

Development Services

Process Development

Each Lonza client is assigned a team of scientists to work with you to transform your process into a closed-system, scalable process that is amenable to cGMP-compliant manufacturing requirement. Your new cell culturing process will be optimized to help ensure that your product maintains its critical quality attributes, which will be validated by customized analytical testing.

Analytical Development

Your designated team of scientists will develop customized tests of your product that can be used for comparability, for information only (FIO), as well as release testing. We have the knowledge and experience to qualify and validate your assays to be used for product release testing.

Media Development

As a tools and service provider, Lonza is uniquely positioned to work with our clients to develop a custom media that will maximize the performance of your product cells. Lonza Custom Medias are formulated to help ensure that they are amenable to closed-system, scalable cell processing.

cGMP-Compliant Manufacturing

Lonza's world-class quality systems can assist with global regulatory compliance of our Cell Therapy manufacturing processes. Incoming raw materials have traceability, with certified CoAs (Certificate of Analysis) in place for incoming resources. Cell Therapy manufacturing suites at all Lonza's sites have unidirectional material movement and personnel flow and are adaptable for your manufacturing technology needs. Our paperless environmental monitoring helps ensure the quality of the manufacturing setting while streamlining batch record documentation. Furthermore, we can address your product labeling and document needs, prepare and approve regulated documents prior to submission, and will gladly consult with the regulatory agencies during audits.

All three of our sites: Walkersville, MD, USA; Verviers, Belgium, EU; and Tuas, Singapore have EU Class B manufacturing suites, custom media manufacturing, as well as on-site QC Testing and QA Specialists.

Biopreservation/Fill & Finish

Biopreservation

The Lonza team's extensive experience includes the formulation and biopreservation of a wide range of product types as well as the optimization and formulation of fresh (non-frozen) cell-based products in order to extend non-frozen shelf-life. We can optimize cryopreservation formulation and freeze parameters to maximize viable cell recovery. Additionally, we offer optimized thawing protocols for clinical trials sites in order to minimize the risks of delayed onset cell death.

Fill & Finish

Lonza offers the filling of closed vials for cell-based products that is scalable to thousands of vials/hour in a cGMP-compliant cleanroom setting. In addition, we offer closed-system bag filling for both autologous products as well as low volume allogeneic products.

Storage and Distribution

Lonza is equipped to establish and maintain a cold chain for your cryostorage needs for both cell banks and product doses. All of our Cell Therapy manufacturing sites maintain a dewar farm for the storage of cell-based products in vapor-phase liquid nitrogen. Our storage warehouse is equipped with redundant automated monitoring systems for the safety and security of all stored MCBs and products. Cell-based products can be distributed globally using dry shippers with temperature monitoring to ensure even and consistent temperature for your product while in transit.

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Viral Therapy

Lonza's Viral-based Therapeutics group specializes in the development and GMP production of viral vaccines and viral vector biologics. Our experienced team has been involved in the manufacture and release of Phase 1 through Phase 3 clinical trial materials for use in the United States, Europe and Asia. For nearly two decades, our relevant industry expertise represents a competitive advantage for our customers. We offer turn-key services for a wide range of product types including viral vectors, live viral vaccines and viral-modified cellular products in our state-of-the-art multi-product Biosafety Level 2 (BSL-2) manufacturing facilities in Houston, Texas USA. Our group has a unique perspective in that its scientific and regulatory teams have both contract manufacturing and relevant product development experience through Biologics License Applications (BLA) and Marketing Authorization Applications (MAA). Lonza's global reach, high-quality facilities, technical capabilities and strong customer focus allow us to be a trusted partner for your viral vaccine and viral gene therapy drug pipeline advancement.

www.lonza.com/viraltherapy

« Relevant Industry Experience »

Development Services

Process Development

The Lonza Viral Team understands the manufacturing challenges facing viral-based therapies and has capabilities that are designed to streamline your product development cycle. By engaging Lonza Viral at an early stage, we will help ensure that the decisions regarding cell lines and the manufacturing process are suitable for later-stage products, thereby saving you time and money as your product progresses through clinical development. We offer process development services suitable for preclinical programs as well as for programs approaching commercial approval.

Analytical Development

The Lonza Viral Team offers a full range of product characterization and release testing for viral vectors and viral vaccines. Our QC Team has practical industry experience in developing and validating a variety of assay types, including product-specific potency assays. We understand the importance of running reference standards in assays. Notably, the Lonza Houston team, through its predecessor company, produced the Adenovirus Type 5 Reference Material (ARM) as a member of the ARM Working Group.

In addition to batch release testing services, we design and perform ICH-compliant stability studies to monitor product integrity over time and/or at multiple storage conditions.

cGMP-Compliant Manufacturing

Lonza Viral offers industry-leading experience for viral-based products from IND to BLA. Few CMOs have the late-stage product development experience offered by the Lonza Viral team, and we understand the complexities and the high level of scrutiny associated with viral-based therapy products from a regulatory standpoint. We provide cGMP manufacturing services from cell and virus banking, to bulk drug substance production and final drug product fill and finish. Our experience in regulatory submissions includes INDs, BLAs (FDA), and MAAs (EMA). Our clients may also reference Lonza Houston's Type V DMF in their regulatory submissions to the US FDA.

Fill & Finish

The Lonza Viral Team has nearly two decades of experience filling viral products for Phase I through Phase III clinical trials. We offer both EU- and US-compliant fill and finish services. As we continue to expand our fill-finish capacity, our current batch sizes range from 100 to approximately 8,000 vials per lot. In addition, we offer flexible scheduling to accommodate your project needs.

Storage and Distribution

Understanding that your products are precious cargo, Lonza Viral offers cGMP-compliant storage services for your cell banks, virus banks and drug products in vapor-phase liquid nitrogen and at temperatures of −80 °C, −20 °C, and 2–8 °C. Our storage facility is alarmed and all personnel access is controlled. Our facilities have backup power and are monitored electronically 24/7.

Distributing clinical materials to study sites is not an easy task. The Lonza Viral team has been managing the distribution of clinical supplies both domestically and abroad for over 10 years. We can help you design and execute shipping/packaging studies and manage any permits required to help ensure that your product is not compromised during transport to your clinical site.

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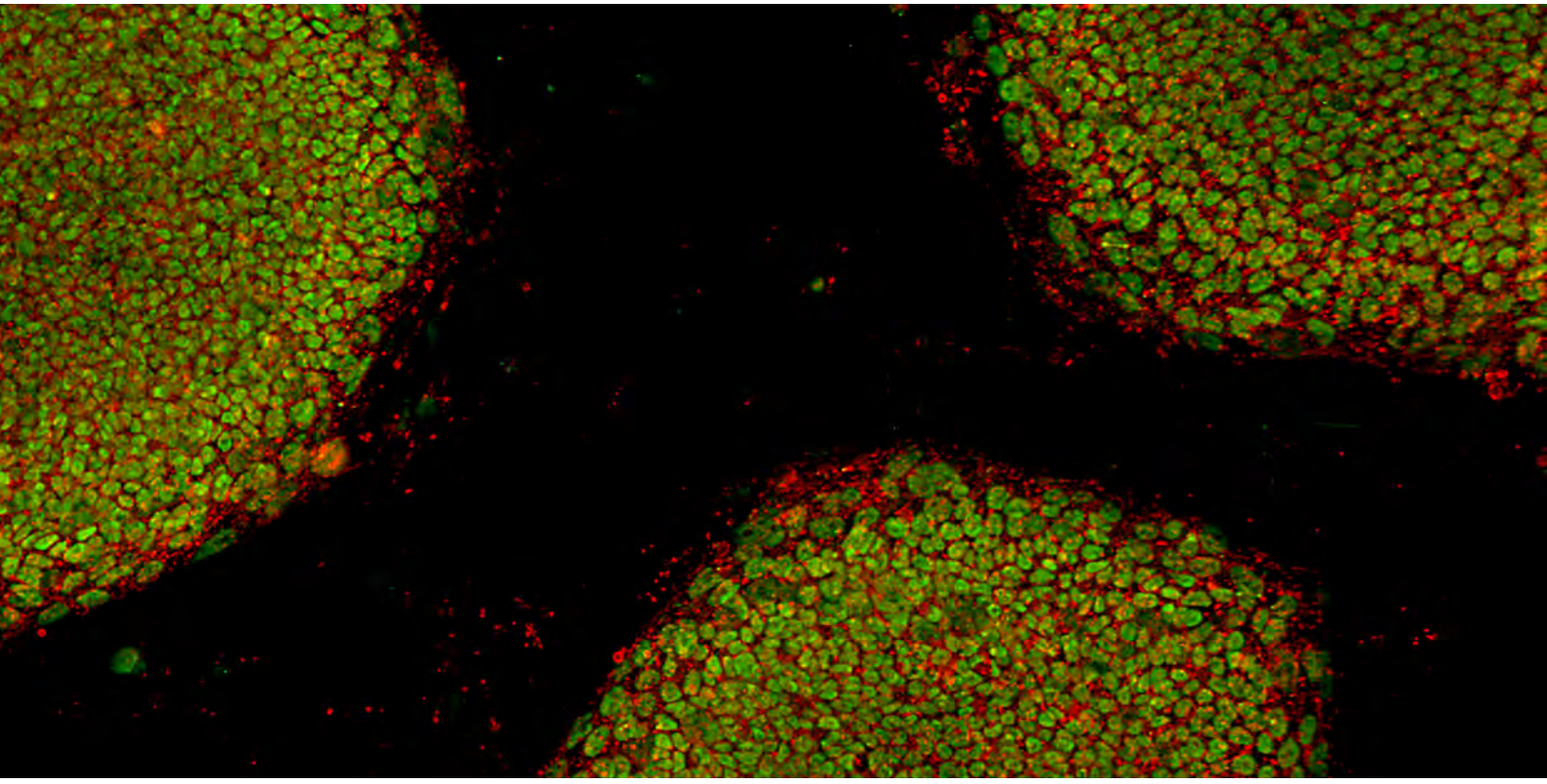
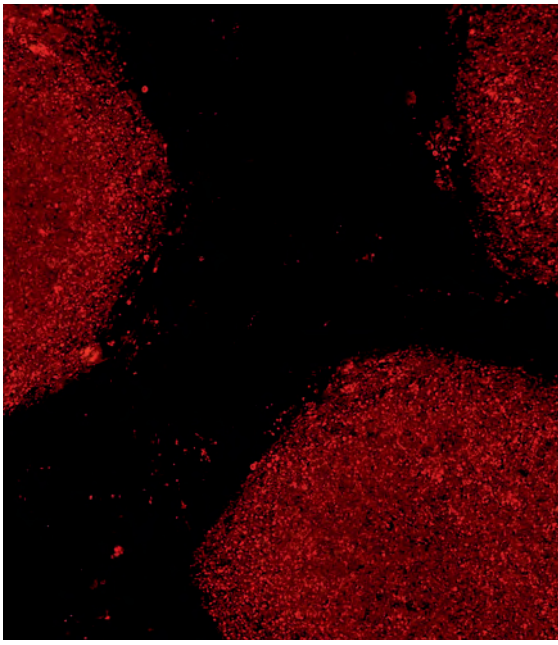


Pluripotent Stem Cell Innovation Center

Both human embryonic stem cells and induced pluripotent stem cells have the ability to generate any of the 220+ cell types in the human body. Due to this unique attribute, Pluripotent Stem Cells (PSCs) have great potential in basic research, drug discovery and cellular therapy. To better serve this emerging market, Lonza has built up expertise, capacity, and capabilities in PSC research and their application to clinical grade manufacturing. Our clients can now access this expertise through our PSC service offering that ranges from iPSC generation to process development and differentiation.



www.lonza.com/pluripotent

« Building Bridges from Research to Therapy »

Pluripotent Stem Cell Services

Tissue Acquisition
We have an experienced team that acquires either research or cGMP-grade tissue in accordance with government regulations and the highest ethical standards.

Reprogramming
We offer cGMP and non-cGMP iPSC generation under feeder- and feeder-free conditions using a zero-footprint technology.

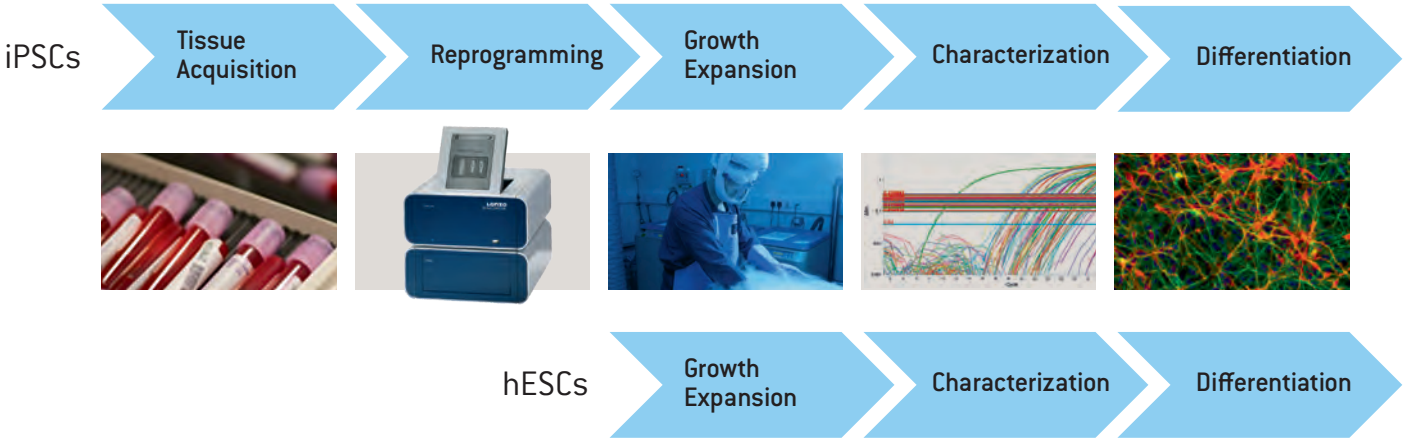
Growth/Expansion/Banking
We have established protocols using all the commonly used medium, matrix, and passaging methods. We also have the infrastructure and resources to support both small and large-scale culture and banking of PSCs for research and clinical applications.

Characterization
We offer all the standard methods of characterizing PSCs including validated methods for mycoplasma and sterility testing, karyotype analysis, short tandem repeat genotyping, pluripotency marker expression, and pluripotency assays.

Differentiation
Our differentiation portfolio consists of protocols for the production of of PSC-derived cell types. We also have on-going development programs for other therapeutically relevant cell types.

Process Development
Over the years we have built up expertise in the differentiation of high purity, functional cell types. Our team is well versed in technology transfer and optimization of production protocols for use in clinical-grade manufacturing.

Lonza's Pluripotent Stem Cell Innovation Center offers services for both research and clinical applications.



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Bioprocessing Media

Bioprocessing Media includes high quality products that provide support to customers who are transitioning from research into a regulated production environment and those who are currently producing regulated protein, cell, or viral therapeutics. Offerings include a full line of mammalian cell culture products, high value specialty media, buffers and reagents. Designed to deliver customizable and efficient solutions for both upstream and downstream processes, Lonza offers powders, liquids and flexible packaging that help meet customers' increasing needs for performance and regulatory compliance.

www.lonza.com/bioprocessing

« Customizable by Design »

Custom Liquid Products

As your partner in your company's product development process, Lonza gives you access to hundreds of cell culture media or buffer formulations with multiple packaging and delivery options. Our rigorous quality control procedures provide premium media, tested to help ensure reproducible results.

The custom liquid process begins with approved and specified raw materials and components, obtained from qualified vendors, which are tested for identity and purity using Near Infra-Red Spectroscopy (NIR). Our insistence on superior-quality materials includes complete NAO (non-animal origin) traceability and our Water for Injection (WFI) system meets both US and European Pharmacopoeia standards.

Standard testing on finished cell culture media or buffers products includes tests for sterility, osmolality, pH, endotoxin content and growth promotion or toxicity. Our broad capabilities help ensure the delivery of appropriate quantity and quality liquid solutions that you need, on time and in cost-effective packaging.

Custom Powdered Products

If you have your own WFI production equipment, then powder is your preferred choice.

Raw material selection is made according to the same high standards as the liquid. Lonza has two state of the art powder facilities, following the same process, and exclusively dedicated to non-animal origin products. Both the US (Walkersville, Maryland) and the Europe facility (Verviers, Belgium) use pin mill technology to reduce particle size and ribbon blenders to help ensure homogeneity.

Part of our release testing includes osmolality, pH, endotoxin content, moisture, dissolution, growth promotion or toxicity. Upon request, HPLC, bioburden, buffer capacity and other testing can be offered.

Customization, Optimization and Creation of Media formulations

Our extensive experience in the interaction between unique primary cells or cell lines and media, positions us as a preferred partner for customization, optimization and creation of new formulations:

- Customization: Modification of an existing Lonza formulation to better fit to your application
- Optimization: Give us your cells, an existing medium, and our R&D lab will optimize the formulation to boost your cell growth and/or productivity
- Creation: Give us your cells, and our R&D lab will design a brand new formulation adapted to your cells

Bioprocess Containers

Platinum UltraPAK™ Bioprocess Containers are made out of a Polyethylene film in a 2-web configuration: an inner layer for product contact (100 % polyethylene) and an outer layer (polyethylene/EVOH/nylon:PVDC blend) for structural support, durability and superior gas barrier properties. Lonza film has been thoroughly validated according to the highest standards. Our bags exist off the shelf in standard with classical connectors (MPC, Luer®…) but can be customized to better fit with your application, using several tubing material, or connectors like needleless injection site, triclover, aseptic connectors and many more.

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Testing Solutions

Lonza offers unique and complementary Testing Solutions for regulated manufacturing needs in cell therapeutic and biopharmaceutical environments. Our portfolio includes the MODA™ Paperless QC Micro Solution and Bioassay and Testing Services and products.

The MODA™ Solution delivers a comprehensive, informatics platform that automates Quality Control (QC) processes for all regulated manufacturing in the Life Sciences industry.

Bioassay and Testing Services are offered along your product development path with immediate support for specific biological assay or custom designed processes. When you need to secure quality, accelerate market entry and navigate constraints, Lonza is your premier partner.

www.lonza.com/bioassayservices
www.lonza.com/moda

« Process Innovation. Integrated Capabilities »

Bioassay Services

The Lonza Bioassay Services team has the experience and expertise to develop and optimize various bioassay methods. Your methods can be custom developed from initial research findings to advanced development of processes and further optimized for method qualification and validation.

We offer also lot release testing, stability testing, cell characterization and potency testing services. Lonza provides you with integral multi-disciplinary support, state-of-the-art GLP/cGMP- compliant facilities and a unique global advantage. By working with Lonza, you will be able to outsource virtually any bioservices function with confidence.

Our Offerings

- Cell proliferation/survival/cytotoxicity-ViaLight/ToxiLight platform
- Stem Cell Characterization & Differentiation (ex. Teratoma formation)
- ELISA-secreted cytokines and growth factors (potency)
- ADCC (Antibody Dependent Cell Mediated Cytotoxicity)
- Angiogenesis – Proprietary immortalized endothelial cell lines
- Proliferation, Migration, Tube Formation
- Neutralization

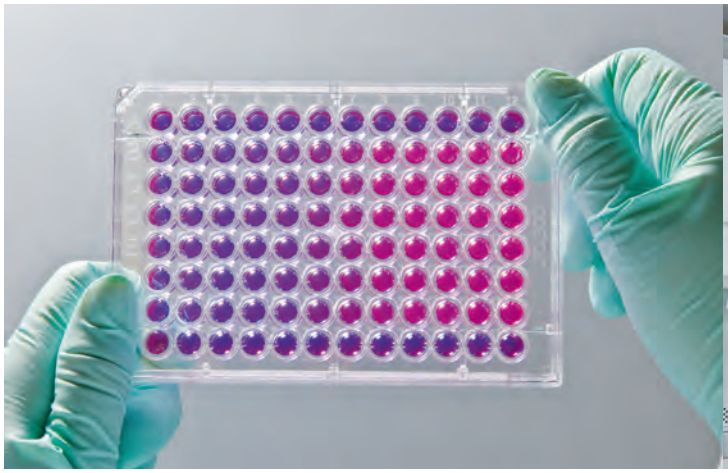
MODA™ Paperless QC Micro Solution

The MODA™ Solution encompasses automation of the full spectrum of QC activities including environmental monitoring (EM), utility testing, and product testing. The MODA™ Software easily integrates with commonly used instrumentation and media found in manufacturing facilities, specifically production and laboratory areas.

Organizations gain timely and accurate QC monitoring by utilizing location based scheduling, mobile data collection, and paperless lab processing. The MODA™ Software also delivers on-demand reporting, trending, and visualization capabilities to allow in-depth process analysis and ad hoc queries by decision makers.

The MODA™ Solution integrates with Laboratory Information Management Systems (LIMS) to bridge the communication gap between QC and production.

More Science. Less Paper.™



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Company Profile

Headquartered in Basel, Switzerland, Lonza is a leading supplier to the pharmaceutics, healthcare and life-science industry. We fuel the possibility of scientific discovery and improve the quality of everyday life. From 1897 to the present day combining Swiss tradition with global experience, the company has had an enterprising character, adapting its offerings and services to the needs of customers and to changing technologies.

Throughout our history, we have maintained a strong culture of performance, results, and reliability. At Lonza, we believe that when you are working to develop treatment, to discover cures, and to enhance lives, you need a partner and supplier you can trust.

Our Vision
We strive to be the leading supplier using science and technology to improve the quality of life.

Our Mission
We work with passion, using advanced technologies, to transform life science into new possibilities for our customers.

Global Presence

Lonza Walkersville, Inc.
8830 Biggs Ford Road
Walkersville, MD 21793

Lonza Houston, Inc.
8066 El Rio Street
Houston, TX 77054

Lonza Biologics Tuas Pte Ltd
35 Tuas South Avenue 6
SG-Singapore 637377

Lonza Verviers Sprl
Parc Industriel de Petit-Rechain
4800 Verviers, Belgium

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